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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,025	06/30/2003	Hirokazu Ohbayashi	239546US0CONT	8296

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EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,025	OHBAYASHI ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears n the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27,32-40 and 47-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27,32-40 and 47-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/24/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's amendment filed on 4/8/2006 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-26, 28-31, 41-46 are cancelled.
2. Claims 47-52 are added to the instant application.
3. Claims 27, 32-40 and 47-52 are under examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 39-40, 51-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 39, this method of making a product lacks active step(s). There is no active step recited for making this product. Applicant merely recites the final structure or relationship of the enzyme to the protein, or the protein to the carrier. Applicant needs to clarify each step of making.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 27, 32-36, 38-40, 47-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnston et al. (EP 0123300, applicant submitted IDS filed on 1/24/2006) as evidence by "Physical Properties of Dextran"(dextran.net updated on 6/28/2006).

Johnston et al. teach a product comprsing carrier-enzmye-protein complex for immunoassay and immunodetection. The complex comprise conjugating enzyme, i.e. glyosidase, or alkaline phosphatase, to a water-soluble dextran carrier, and then conjugating protein, e.g. biotin, avidin or streptavdine, to the enzyme where the protein does not conjugated directly to the carrier, and the said protein is free to bind to substance, such as antigen or antibody (See page 3, line 22 to page 4, line 20; claims 1-7).

With respect to claims 32 and 39, Johnston et al. also teach manufacturing such complex (See example 1 and example 2).

With respect to claims 33-36, the protein conjugating to the enzyme is free to bind to antibody, antigen or sugar chain. Surpa.

With respect to claim 38, Johnston et al. teach using avidin as the protein which can bind to biotin. Surpa.

With respect to claims 47-52, the carrier used by Johnston et al. is dextran which is water-soluble and having wide range of molecular weight, e.g. from 1000 dalton to 2000000 daltons (See "Physical Properties of Dextran"-from dextran property, dextran.net updated on 6/28/2006).

5. Claims 27, 32-36, 38-40 and 47-52 rejected under 35 U.S.C. 102(e) as being anticipated by Ohbayashi et al. (US 6252053).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Ohbayashi et al. teach a product comprsing carrier-enzmye-protein complex for immunoassay and immunodetection. The complex comprise conjugating enzyme, i.e. glucose oxidase, or alkaline phosphatase, to a water-soluble aminodextran carrier, and then conjugating protein, e.g. biotin, avidin or streptavdine, to the enzyme where the protein does not conjugated directly to the carrier, and the said protein is free to bind to substance, such as antigen or antibody (Col. 2, line 45-65; claims 2).

With respect to claims 32 and 39, Ohbayashi et al. also teach manufacturing such complex (See example 1 to example 4).

With respect to claims 33-36, the protein conjugating to the enzyme is free to bind to antibody, antigen or sugar chain. Surpa.

With respect to claim 38, Ohbayashi et al. teach using avidin as the protein which can bind to biotin (See example 4).

With respect to claims 47-52, the carrier used by Ohbayashi et al. can be polylysine or polysaccharide which is water-soluble and having wide range of molecular weight, e.g. from 5000 dalton to 500000 daltons (See claim 5, 10 and Col. 3, line 25-38).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Johnston or Ohbayashi et al. in view of Chichibu et al. (US 5019498).

Johnston and Ohbyaashi et al. reference have been discussed for detecting various target molecules but does not explicitly teach using protein specific for hyaluronic acid.

Chichibu et al. teach using hyaluronic acid specific binding protein to detect hyaluronic acid because hyaluronic acid is a marker for inflammatory disease, such as rheumatism (See Abstract).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided either Johnston or Obhyashi et al. with the hyaluronic binding protein to detect hyaluronic acid molecules in a sample as taught by Chichibu et al. because Bohannon et al. already disclose a general immunoassay by using the complex and detecting a specific target molecule merely involves routine skill in the art.

Response to Applicant's Arguments

3. Applicant's arguments with respect to claims 27, 32-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

4. No claim is allowed.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu
Examiner
Art Unit 1641

June 28, 2006

LONG V. LE
SUPERVISORY PATENT EXAMINER
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